REMARKS

By the above amendments, the specification has been amended, an Abstract has been added, claims 1-14 have been canceled and new claims 15-28 have been added. An Information Disclosure Statement is also being filed herewith under separate cover letter citing the International Search Report in the parent International Application and the references referred to in the Search Report.

An early action on the merits is requested.

Please charge any shortage in the fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account No. 01-2135 (500.36515VX1) and please credit any excess fees to such deposit account.

Respectfully submitted,

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Marked-up Version

Device for Administering a Proton Therapy

Related Application

This application is a Section 371 filing based on International Application PCT/CH00/00334 filed June 20, 2000, the priority of which is claimed under 35 USC §120. A claim for priority under 35 USC §119 is in turn made to Switzerland Application No. 1180/99, filed June 25, 1999.

Field

This invention relates to a device for administering proton therapy to human patients as well as various improvements designed to increase safety, to improve and simplify process control, to enhance patient acceptability, and also to allow the device to be constructed to smaller dimensions; the invention also relates to an application [or a] of the device

Background

Proton therapy, especially that intended for the treatment of cancers, is becoming increasingly important since it entails significant advantages in

comparison with the photon-radiation therapy in widespread use.

Although equipment for administering proton therapy has been known since the mid-fifties in the U.S., up to now such therapies have been utilized worldwide only at a few centers such as research institutions. This circumstance is due first to the fact that proton accelerators required are still quite expensive, and secondly to the fact that the proton therapy equipment necessary for administering an efficient and safe therapy is quite large and complex. The first and only purely hospital-based proton therapy device is located in the U.S. at the Loma Linda University Medical Center in California. Additional units are in the process of being put into operation in Boston (U.S.) and Kashiwa (Japan).

Unlike the above device at the Loma Linda University Medical Center in which the proton therapy is performed using a so-called scattering method, a proton therapy device was developed at the Paul Scherrer Institute in Würlingen, Switzerland, which utilizes the so-called spot-scanning method. In this connection, reference is made to the article by Eros Pedroni et al. in Med. Phys. 22 (1), January 1995, pages 37—53 with the title 'The 200-Mev

Proton Therapy Project at the Paul Scherrer Institute: Conceptual Design and Practical Realization." This article refers to the fundamental principle of the above-mentioned spot-scanning method and to a device described using the term 'gantry," with which device proton therapy has now been administered to patients for about three years . Although the outside dimensions of the device at the Paul Scherrer Institute were able to be reduced relative to the device at the Loma Linda University Medical Center by using the so-called spot-scanning method, this device still has a diameter of about 4 m, and has the additional disadvantage that access to patients during treatment is unsatisfactory. A detailed description of the device at the Paul Scherrer Institute may be dispensed with by citing the above reference in the literature, which reference is an integral part of the present patent application.

In European Patent Applications EP 0 864 337 and EP 0 911 064, similar arrangements for treating a patient by proton therapy are described, which are partially based on the device developed at the Paul Scherrer Institute or describe similar or the same treatment methods.

The preferred position for a patient is the supine position so as to preclude any deformation of the organs during treatment. Therapy must therefore allow accessibility from all sides and encompass the entire human body; for this reason, the generally known proton therapy devices, including that at the Paul Scherrer Institute, are designed so that the entire proton beam guiding device housing is rotatable 360° about a central axis around the so-called patient table, with the result that the device may have a diameter of between 4 and 12 meters. Especially when treating a patient from below, the proton beam guiding device must be moved under the patient table, or the patient table must be raised to a position several meters above the actual level of the working base. The resulting specific disadvantages may also be found in the above-cited literature reference on page 49 in chapter IV, D4 which cites the problems entailed by raising the patient table in this way. This positioning process is critical, and in the event the device experiences an accident during treatment, a special crane device is required to extract or manage the patient. While this disadvantage may be alleviated by providing a relatively deep shaft under the patient table, this approach creates a risk of accidents, such as the person treatment the patient falling into this shaft.

Summary

The object of this invention is thus to propose measures by which the operation of proton therapy may be simplified and made safer, and in which preferably the outside dimensions of the device may be reduced.

[According to the invention, this] This object is achieved by [a] the proton therapy device [particularly according to Claim 1] or apparatus of the invention, and by means of a method for treating a patient according to the invention using the proton therapy [device according to Claim 11] apparatus.

The invention proposes that a proton beam guiding and control device, or a proton beam guiding device housing located in the treatment arrangement, not be rotatable by a full 360° around a patient table, unlike the "gantry" of the Paul Scherrer Institute, described in the literature, but that the rotational movement be limited to approximately 270°. Here the rotation occurs essentially about a horizontal axis of rotation, in which axis of rotation generally a controllably movable patient table is located in the starting position. This limitation to 270° results in a region through which the beam guiding and control device is not freely movable, in which region the patient

table is freely movable and always readily accessible. It is this accessibility to the patient table in particular which represents an essential improvement provided by this invention since the person providing treatment may always access the patient without danger or obstruction.

The result of this preferred arrangement of the proton beam guiding and control device in which the device is rotatable starting from the horizontal plane running essentially through the axis of rotation both upwards and downwards by approximately 135° about the axis of rotation, or from - 90° to +180° from the vertical, is that the patient table is readily accessible from the opposite side. The patient table is thus freely movable within the above-mentioned horizontal plane or within a horizontal plane designed to run nearly parallel to this plane - for example, specifically rotatable by at least 180° about an axis which runs essentially through the isocenter of the proton beam guiding and control device. The isocenter is formed on the one hand by the proton beam exiting the proton beam guiding and control device, and on the other hand by the axis of rotation about which this device is rotatable.

The result of this arrangement according to the invention is first of all, as

already mentioned, that the patient table is always readily accessible, and secondly that despite this accessibility treatment of the patient from all sides is possible since first of all treatment both from above and below is ensured, as is treatment from both sides, the treatment being enabled by rotating the patient table by 180°.

Preferred variant embodiments of the arrangement according to the invention are characterized in the dependent claims.

[Applications of the arrangement according to the invention are characterized in Claims 11 *et seq.*]

To provide a fuller understanding of the invention, an example of a proton beam treatment device according to the invention is described in more detail based on Figs. 1—3[, wherein:].

Brief Description of the Drawings

Figure 1 is a perspective view of a proton beam treatment device for

treatment of a patient from the side.

Figure 2 shows the device in Figure 1 for treatment of a patient from above.

Figure 3 shows the device in Figure 1 for treatment of a patient from below.

Detailed Description

Figure 1 shows in schematic and simplified form a device or apparatus 1 for treating a patient using proton beam therapy. Here the proton beam 3 is directed by quadrupoles 5 and magnets 7 to the actual end-mounted proton beam guiding and control device 9. Located on the front face of this proton beam guiding and control device is an exit window 11 or so-called 'nozzle" through which the proton beam exits and is directed to the patient. The proton beam may be deflected horizontally within a narrowly limited angle by an additional deflection magnet arrangement 6, also called a 'sweeper magnet." At the same location, the drawings show a second 'sweeper magnet" which may be used as an option to effect a rapid magnetic motion of the beam — but one which is limited by the aperture of the 90° magnet. Also located in the region of exit window 11 and not visible in Figure 1 is a

penetration depth adjustment device, also called a 'range shifter," by which the penetration depth of the proton beam into the body of the patient may be set. It is important here to again refer to the article by Pedroni et al. cited in the preamble which describes the basic principles of operation for a proton beam therapy device such as the so-called "gantry" at the Paul Scherrer Institute.

Also shown in Figure 1 is a guide rail 13 on which is arranged the proton beam guiding and control device 9 so as to be movable about a central axis of rotation. Protruding through lateral shielding guides 15, the exit window 11 moves in a slit-like opening 17 along mounting device 13 when the guiding and control device (9) is moved.

A patient table 21 is arranged to lie in a horizontal plane, running essentially through the axis of rotation of the guiding and control device. This table is movable about an axis of rotation and on a mounting device 23 along a guide 24, this guide being located on a working platform 25. The rotation of patient table 21 proceeds preferably here about an axis of rotation which runs essentially through the head region 27 of patient table 21, and which

axis of rotation runs mainly through the region of the so-called isocenter of the device. It is of course possible to have the horizontal plane in which the patient table 21 is located also run parallel a certain distance above or below the horizontal plane through which the rotational axis of proton beam guiding and control device 9 runs. This distance should be restricted, however, so as to ensure that proper treatment is possible from above and below, and additionally to allow the patient table to be capable of being accessed at a suitable height from working platform 25 by the person providing treatment. It is of course also possible to have patient table 21 be arranged on mounting device 23 so as to be both adjustable vertically and slidable in the longitudinal and transverse axes of the table.

The rotatability of the patient table should encompass an angle of at least 180°, although it is clearly evident from Figure 1 that an angle greater than 180° is not feasible for reasons of design and is also not necessary. According to another special variant embodiment, it is also possible to design the patient table to be rotatable about another axis of rotation, for example, around a vertical axis of rotation running through the center of the table. This rotation is necessary or useful, for example, when a patient is to

be treated in the leg region and this region must thus be aligned with the isocenter of the device to allow, for example, a tumor in one leg to be treated accordingly by the proton beam.

Figure 2 shows the same device as in Figure 1 with beam guiding and control device 9 in the top orientation. In other words, in the arrangement of Figure 2 the proton beam treatment is administered from above, while in addition the patient table is in a position different from that in Figure 1. In addition, Figure 2 clearly shows that the patient table is slidable in the longitudinal axis of the table.

Finally Figure 3 shows yet another position attainable by beam guiding and control device 9 where treatment of the patient is administered from below.

The fundamental advantage of the device described according to the invention over the known 'gantry" at the Paul Scherrer Institute is immediately evident in the fact that the patient table, for example, does not need to be raised significantly to administer treatments from below and that as a consequence accessibility to the patient table for the person providing

treatment is always ensured. This feature has advantages not only for a patient receiving treatment but also for a person providing treatment since with the device according to the invention there is no longer any risk of accidentally falling into a shaft.

An additional problem associated with existing proton treatment devices is encountered in the region of the exit window of the proton beam housing, also called the 'nozzle" in English and in technical parlance. Located in the region of this exit window in the device described in the introduction above is a penetration depth adjustment device, also called a 'range shifter" with which the penetration depth of the proton beam is controlled very precisely since the energy required to destroy a malignant organ or tumor is released precisely at the end of the range of the proton beam.

In practice it has been found that the proton beam is disturbed by the air gap between the so-called 'range shifter" and the patient, thereby degrading the precision of beam control at least slightly.

For this reason, the invention also proposes locating this adjustment device

for modifying the range of the proton beam, or the so-called 'range shifter," no longer in the region of the output window or the so-called 'nozzle" on the proton beam guiding housing, but instead before the entry of the proton beam into the guiding housing in which the proton beam is guided, in known fashion, to the patient and to the so-called 'spot" receiving treatment. With respect to Figure 1, this means that the so-called 'range shifter" is no longer located in the region of exit window 11 but placed before the treatment arrangement 1, as Figure 4 shows schematically, specifically with reference number 31.

Placing the so-called "range shifter" before the following proton beam guiding device within the treatment arrangement does, however, have the effect that in conjunction with this design magnetic arrangements 7, or the magnet arrangement in the end-mounted proton beam guiding and control device housing 9, must be made variable in order to compensate for an increased or attenuated energy of the proton beam so that the proton beam may ultimately be in turn directed to the desired spot in the patient. However, this is no problem using the currently known process controls or known computer controls, while on the other hand the above-cited problems

connected with the precision of beam control may be significantly improved by simplifying the design of the exit window.

The usual procedure for the required destruction of the malignant cells in an organ or in a human body is to move the patient table relative to the proton beam guiding housing in discrete steps so as to allow the proton beam to scan the entire region in the organ or human body point by point. This motion of the patient table is necessary since the 'sweeper magnet" and 'range shifter" move the proton beam only in two directions, or two—dimensionally, so that the patient table must be designed to be movable to accommodate the spatial treatment of a region in a patient, or to accommodate the third dimension. With the selected spot—scanning method, this motion of the patient table is not continuous but occurs, as mentioned, in discrete steps. This discrete motion is often viewed as disadvantageous or awkward, especially by the attending physicians or persons providing treatment.

For this reason, another variant embodiment of the proton therapy device according to the invention proposes a covering housing in the region of the

exit window or so-called "nozzle" in which all the devices required for dosing and control or shielding, and elements for controlling the proton beam, are located out of sight. With respect to the motion, this housing itself is coupled to the patient table through a control device such that the discrete movements of the table are also effected by this covering housing and for the patient no relative motion with respect to the proton beam guiding housing occurs. An additional advantage of including such a covering housing is the fact that the relative position of a contact-hazard-protection device, which may be integrated with the housing, always ensures optimum protection in the event the patient table is to be moved relative to the exit window or the 'nozzle." Such a protection device may thus be located within the housing where it can interrupt the proton beam within fractions of a millisecond.

The advantage of including such a covering housing is also the fact that, for example, the collimators and compensators required for concentrating and focusing the proton beam in other known devices, for example, those using the so-called scattering method, may be located in such a housing. The controlled coupling of the covering with the patient table ensures in this case that even when the patient table is moved the proton beam always remains

directed at the proper spot in the body of the patient body.

With respect to Figure 1, this means that the housing 11 of the exit window, shown schematically, is not attached to proton beam guiding and control device 9 but is controlled to move also synchronously with the movements of the patient table. It is possible here to couple the movements of covering housing 11 with those of patient table 21 by using a control device so that no relative motions between the housing and the table take place when patient table 21 is moved during treatment of the patient.

The improvements proposed according to the invention for a proton beam treatment device, especially one utilizing the spot-scanning method such as the so-called 'gantry" at the Paul Scherrer Institute, result in significant simplifications in the operation of the device as well as enhancements in the safety and user acceptability of the device, both for patients as well as for the operating personnel.